

AR201-14061



RECEIVED
OPPT NCIC

Walter Jones <wjones@pinechemicals.org> on 11/06/2002 10:28:43 AM

2002 NOV -8 AM 10: 52

Please respond to wjones@pinechemicals.org

To: NCIC OPPT/DC/USEPA/US@EPA, Rtk Chem/DC/USEPA/US@EPA

cc:

Subject: RESPONSE TO PETA REGARDING PINE CHEMICALS ASSOCIATION, INC. TEST PLAN FOR ROSIN ESTERS

Attached please find a copy of the subject response. A hard copy was mailed on October 31, 2002

Walter L. Jones, President & COO

Pine Chemicals Association, Inc.

v 770.399.3112

f 770.399.3115

www.pinechemicals.org



- peta.doc

October 31, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attention: Chemical Right-to-Know Program

Re: Response to PETA Regarding Pine Chemicals Association, Inc. Test Plan for Rosin Esters

Dear Ms. Whitman:

The Pine Chemicals Association, Inc. (PCA) HPV Task Force has recently reviewed the comments on its Test Plan for Rosin Esters from the People for the Ethical Treatment of Animals (PETA), dated October 14, 2002.

Although PETA's comments address a variety of issues related to the rosin esters test plan, their goal is aimed at minimizing unnecessary experiments on animals. PCA agrees with this objective, and wants to inform EPA and PETA regarding the efforts we have undertaken to minimize animal testing in our rosin esters test plan and in all of our efforts under the HPV Program.

As PETA knows, the PCA HPV Task Force and its members have sponsored thirty-six (36) chemicals in the HPV Program. Our efforts began with an extensive literature search to find existing data. We also gathered data from our member companies in order to minimize the amount of new testing that would be required under the HPV program. PETA's contention that we failed to maximize use of existing adequate data to minimize testing is incorrect. It is in our interests, as well as PETA's, to maximize the use of available data, and PCA made every effort to do so.

Next, we reviewed the chemistry, structures, and composition of the sponsored chemicals in order to determine how the chemicals could be grouped in a scientifically supportable manner. Our scientists, including chemists, toxicologists and persons knowledgeable in the process and uses of these chemicals, reviewed the 36 substances and concluded that 6 categories would be required to fairly represent the range of properties of the sponsored chemicals. PCA has been a leader in the use of

the category approach under the HPV program, and EPA has approved the six categories we proposed. PETA argues that we failed to maximize the use of categories; this reflects a scientific disagreement about how broadly one substance can represent another substance.

We followed EPA's guidance on developing chemical categories and used the family approach (although not as broadly as PETA would have liked) to form our proposed categories. PETA takes issue with three of these categories -- rosins, rosin adducts and rosin esters -- and recommends they should be collapsed into one. We want to stress that we considered this approach extensively prior to submitting the current Test Plans. Our scientists reviewed the properties of the substances and the existing data to determine if all nineteen (19) rosin-based chemicals could be grouped together as one category. Unfortunately, our scientists did not believe that one category of all 19 substances was scientifically supportable due to fundamental differences in their chemical composition. EPA staff concurred in this assessment in discussions regarding our plans. Nothing in PETA's comments presents scientific information to support grouping the rosins, rosin adducts and rosin esters together.

Once the categories were established, along with their representative substances, PCA carefully researched all of the protocols in order to minimize the use of animals for any missing endpoints. PETA's comments appear to ignore these efforts. For example, PETA suggests PCA incorrectly listed the wrong protocol number for testing the developmental endpoint for rosin, pentaerythritol ester. However, PCA purposefully proposed to conduct OECD 421 -- rather than OECD 414 -- in order to minimize the use of animals. Likewise, PCA chose OECD 422, which is a combined repeat-dose and developmental/reproductive, to fulfill the required endpoints for rosin, partially hydrogenated, methyl ester -- rather than perform the tests separately under OECD 421 and 407. We agree with PETA that developmental toxicity "is not an issue" for these substances. We agree with PETA that our substances are "relatively non-toxic." Unfortunately, the HPV program does not provide an exemption from testing for non-toxic substances.

PETA also suggests that PCA use the *in-vitro* dose range-finding protocol prior to conduct *in-vivo* testing in order to save additional animals. We first note that this protocol is recommended only for range-finding for the acute toxicity testing. Based on available scientific information, range-finding was not necessary. Thus, use of the *in-vitro* range-finding procedure is not necessary. PCA has investigated the potential use of the *in vitro* procedure for other substances, and ascertained that there are virtually no laboratories capable of performing this procedure, and no formal validated OECD protocols available.

PETA also suggested that PCA forego aquatic toxicity testing in favor of modeling using methods such as ECOSAR or TETRATOX. While we understand the motivation behind PETA's suggestion, we note that neither of these models has been recognized as part of the SIDS or HPV program. Accordingly, we are not allowed to use these methods as part of the HPV Program. These models also do not lend themselves to application to complex mixtures such as the PCA Class 2 chemicals.

PETA notes that rosin esters are unlikely to be bioavailable to aquatic life, and therefore takes issue with our proposed aquatic testing. Again, we agree that our substances are not likely to harm aquatic life, but find no exemption in the HPV program on this basis. The proposed methodologies for our aquatic testing are consistent with OECD (2000) Guidance Document 23 for difficult to test substances.

PCA appreciates the opportunity to respond to PETA's comments on these important issues. In developing our test plan, our scientists spent many hours collecting and reviewing existing data and discussing the issues raised by PETA. We have attempted to minimize the use of animals to the extent it is scientifically defensible.

Respectfully submitted,

Walter L. Jones
President & COO